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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SCHWADRON, RONALD B

ART UNIT PAPER NUMBER

1644

DATE MAILED: 01/09/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/767,578

Applicant(s)

Trakt

Examiner

Ron Schwadron, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 8, 13-39, 47, 60, and 61 is/are pending in the application.
- 4a) Of the above, claim(s) 1, 2, 8, 13-28, 35-39, 47, 60, and 61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

1. Applicant's election with traverse of Group V, claims 29-34 in Paper No. 5 is acknowledged. The traversal is on the ground(s) that are stated in said paper. This is not found persuasive because of the following reasons. Regarding applicants comments, the USPTO interprets independent and distinct as reading on independent or distinct (see M.P.E.P. 802.01 and 803). The MPEP section 803 states:

Restriction - When Proper

Under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP § 806.04 - § 806.04(I)) or distinct (MPEP § 806.05 - § 806.05(I)).

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

CRITERIA FOR RESTRICTION BETWEEN PATENTABLY DISTINCT INVENTIONS

There are two criteria for a proper requirement for restriction between patentably distinct inventions:

(A) The inventions must be independent (see MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(I)); and

(B) There must be a serious burden on the examiner if restriction is required (see MPEP § 803.02, § 806.04(a) - § 806.04(I), § 808.01(a), and § 808.02).

The Office Action mailed 9/25/2002, paragraphs 2-8 explains why inventions I-VII are distinct.

Regarding applicants comments on page 3 of the instant amendment, the M.P.E.P. § 803 states that: "For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search". The restriction requirement enunciated in the previous Office Action meets this criterion and therefore establishes that serious burden is placed on the Examiner by the searching of additional Groups. The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1,2,8,13-28,35-39,47,60,61 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions, the requirement having been traversed in Paper No. 5.

3. The abstract of the disclosure is objected to because according to 37 CFR 1.72 (as per post AIPA changes) the abstract needs to be no more than 150 words. Correction is required. See MPEP § 608.01(b).

4. Applicant needs to update the status of application 09/040833 disclosed in the first paragraph, page 1 of the specification (eg. Now US Patent 6197582).

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the trioma cell ATCC HB 12482 is required to practice the instant invention as recited in claim 34. As a required element, said clone must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If said clones are not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the cell line. See 37 CFR 1.802.

The specification does not provide a repeatable method for obtaining trioma cell ATCC HB 12482. There is no guidance in the specification as to how to produce a trioma identical to ATCC HB 12482. Deposit of said trioma would satisfy the enablement requirements of 35 U.S.C. 112. In addition, the identifying information set forth in 37 CFR 1.809 (d) should be added to the specification. See 37 CFR 1.801-1.809 for additional

explanation of these requirements. While said cell line has been deposited under provisions of the Budapest treaty the requirements under 37 CFR 1.808 has not been met. The requirements under 37 CFR 1.808 can be met by submission of an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability of the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements.

7. Claims 29-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the . . . claimed subject matter", *Vas-Cath, Inc. V. Mahurkar*, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of the claimed invention.

The instant claims encompass use of a trioma with the functional characteristics of claim 2, wherein said trioma can be used to produce antibody secreting tetromas. The specification discloses a single example of such a trioma. The claims encompass use of any trioma with the aforementioned functional attributes wherein said claims would encompass use of a vast array of different cell lines and wherein there is no biochemical properties of such cell lines disclosed in the specification that would result in the particular functional attributes that the trioma cell must possess to function in the claimed method. Thus, the written description provided in the specification is not commensurate with the scope of the claimed inventions. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See *The Regents of the University of California v. Eli Lilly and Company*, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In

University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, *id.* at 1240. In the instant case, the specification has disclosed a method using a single example of a trioma with the pertinent functional attributes while claiming any trioma for use in said method. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . . conception has not been achieved until reduction to practice has occurred", *Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd.*, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of *The Regents of the University of California v. Eli Lilly and Company* (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 29-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention.

Claims 29 and 30 are indefinite in that they depend from a nonelected invention (eg. claim 2).

10. It is noted that the specification defines "trioma" as a cell line formed from the fusion of three cells wherein a human-murine hybridoma is fused with a human lymphoid cell (see page 23, lines 19-24).

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oestberg et al. (US Patent 4,634,664).

Oestberg et al. teach xenogeneic hybridoma fusion partners that do not produce antibody and the use of said cells as fusion partners to produce monoclonal antibodies upon fusion with an antibody producing cell (see column 2, last paragraph and column 3). Oestberg et al. teach that the nonantibody producing xenogeneic hybridoma fusion partner can be made by fusing a myeloma cell to a human lymphocyte (see column 2, last paragraph, continued on column 3). Oestberg et al. teach that the myeloma cell used can be a hybrid cell formed from the fusion of two cells(see column 2, last paragraph). Thus,

Oestberg et al. teach use of a three cell containing xenogeneic hybridoma fusion partner that does not produce antibody and the use of said cells as fusion partners to produce monoclonal antibodies. Oestberg et al. do not teach that the cell is a trioma as per the definition of the term in the specification (eg. "trioma" as a cell line formed from the fusion of three cells wherein a human-murine hybridoma is fused with a human lymphoid cell). Oestberg et al. teach heteromyeloma cell fusion partners (eg. mouse/human fused cells, see claim 14). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have produced the claimed method because Oestberg et al. teach the claimed method except for use of a trioma cell line formed from the fusion of three cells wherein a human-murine hybridoma is fused with a human lymphoid cell, Oestberg teach use of three cell nonantibody producing xenogeneic hybridoma fusion partner containing a hybrid myeloma cell and Oestberg et al. teach human heteromyeloma cells (mouse human hybrid myeloma cell line). One of ordinary skill in the art would have been motivated to do the aforementioned because Oestberg et al. teach use of hybrid myelomas as the fusion partner with a nonantibody secreting human lymphocyte (see column 2, last paragraph, continued on next page) to form a three cell nonantibody secreting fusion partner and also teaches heteromyeloma cell fusion partners (eg. mouse/human fused cells). The antibody producing hybrid cells can be used in vitro or in vivo to produce antibody (see claim 18). The cells are grown in vitro under conditions in which antibody is produced (see examples). Oestberg et al. teach freeze storage of desired antibody secreting cells (see column 7, penultimate paragraph). The various assay steps recited in claim 30 involve art known steps for immunoassays (see Examples in Oestberg et al.). The condition recited in claim 30 could be any of the art known diseases disclosed in column 4 of Oestberg et al.

13. No claims is allowed.

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

15. Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.



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